HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

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AIDS	acquired immune deficiency syndrome
CA	cooperating agency
CDC	U.S. Centers for Disease Control and Prevention
CIF	cost, insurance, and freight (insurance and shipping charges are all included in a CIF price)
DHIV	Division of HIV/AIDS [USAID]
ECHO	Equipment for Charitable Hospitals Overseas
FDA	U.S. Food and Drug Administration
FOB	free on board (insurance and shipping charges are not included in an FOB price)
HIV	human immunodeficiency virus
IDA	International Dispensary Association
IDPIG	*International Drug Price Indicator Guide* [MSH]
MSH	Management Sciences for Health
NGO	nongovernmental organization
RPM	Rational Pharmaceutical Management (Project)
RPM Plus	Rational Pharmaceutical Management Plus (Program)
U.S.	United States of America
USAID	U. S. Agency for International Development
USAID/W	USAID/Washington, D.C. office
USD	U.S. dollars
VCT	voluntary counseling and testing [for HIV]

Efficacy	**Efficacy** is the ability of a drug or a pharmaceutical product to produce a purported effect as determined by scientific methods.
FDA approval	**FDA approval** means that the product has met the standards of the U.S. Food and Drug Administration for safety, efficacy, and quality for the proposed application.
Origin	The **origin** of a pharmaceutical product is the country in which it is produced.
Pharmaceutical products	**Pharmaceutical products** include drugs, vitamins, oral rehydration salts, biologicals, and some in vitro diagnostic reagents/test kits (including HIV test kits and antibiotic susceptibility testing kits) for the purpose of USAID procurement regulations.
Quality	The **quality** of a pharmaceutical product is determined by its identity, purity, potency, uniformity of dosage form, bioavailability, and stability. For HIV test kits quality determinants include identity, purity, stability, sensitivity, specificity, and time taken to produce a result.
Safe medical product	FDA defines a **safe medical product** as one that has reasonable risks given the magnitude of the benefit expected and the alternatives available.
Sensitivity	**Sensitivity** of a test is the probability of testing positive if infection/disease is truly present. As the sensitivity of a test increases, the number of false negatives decreases.
Source	The **source** of a product is the country a commodity is shipped from and does not include free ports or bonded warehouses. The source can be the cooperating country, if that is where the commodity is located at the time of purchase.
Specificity	**Specificity** of a test is the probability of testing negative if infection/disease is truly absent. As the specificity of a test increases, the number of false positives decreases.

A. Background and Objective

Starting in the late 1990s, the U.S. Agency for International Development (USAID), Division of HIV/AIDS (DHIV) has been called upon by USAID Missions and USAID-funded cooperating agencies (CAs) to provide assistance in the procurement of rapid HIV diagnostic test kits for use in HIV voluntary counseling and testing (VCT) programs. VCT provides an entry point for an extended range of support, care, and prevention activities for HIV/AIDS. Rapid HIV test kits permit same-day HIV testing, allowing patients to obtain their results before leaving the clinic. Studies have shown that a significant number of clients do not collect their results if they must return at a later time. Consequently, DHIV has identified the procurement of HIV test kits as a primary objective in support of its strategy to scale up country-level VCT programs for USAID's expanded response initiative to the HIV/AIDS pandemic.

Until 1998, the U.S. Centers for Disease Control and Prevention (CDC) recommended withholding the results of an initially positive HIV test result until a confirmatory Western blot test report had been received, so market demand for rapid HIV test kits in the United States was low. As a consequence, manufacturers of rapid HIV test kits had little incentive to apply for FDA approval. Although CDC revised its recommendations in 1998 and encouraged wider use of rapid HIV testing, many of the rapid HIV test kits presently included in the HIV testing algorithms of developing countries are not available from U.S. sources or are not of U.S. origin, and very few are FDA approved. Additionally, the complexity of the process to prepare requests for approval to procure rapid HIV test kits in view of the "Buy America" objectives of USAID procurement procedures, and the need for USAID to be confident of the quality, safety, and efficacy of all pharmaceutical commodities purchased with USAID funding, resulted in delays in procuring USAID-funded HIV test kits to support VCT programs.

In 2000, DHIV requested assistance from the Rational Pharmaceutical Management (RPM) Project to review the guidelines and procedures for USAID-funded procurement of HIV/AIDS-related pharmaceutical products. RPM findings and recommendations are outlined in a report entitled *USAID-Funded Procurement of HIV/AIDS-Related Pharmaceutical Products: Constraints and Options for Improvement*.[1] During the development of that report, the lack of information on suppliers and sources of non-U.S. source/origin pharmaceutical products was identified as a constraint by some USAID-funded CAs. In January 2001, the USAID Administrator approved a source and origin waiver for HIV/AIDS diagnostic materials (testing kits)[2] to facilitate the process to obtain approval to procure the HIV test kits listed in Tab 1 of the source/origin waiver.

DHIV also provided funding to the Rational Pharmaceutical Management Plus (RPM Plus) program, RPM's successor, to develop this procurement information document to assist USAID Missions and CAs in identifying manufacturers and international agencies/suppliers of HIV test kits listed in Tab 1 of the source/origin waiver. The objective of this document is to facilitate the

[1] Keene, Douglas, and Helena Walkowiak (2000). Published for USAID by Rational Pharmaceutical Management Project. Arlington, VA: Management Sciences for Health.

[2] For the text of the USAID source and origin waiver for HIV/AIDS diagnostic materials (testing kits), see annex 1.

process for USAID Missions and CAs to procure HIV test kits for their programs. This document also contains additional information to assist Missions and CAs with planning for procurement, including information on prices, shelf life on delivery, and the source and origin of the product.

B. Methodology

To develop this document, RPM Plus surveyed the manufacturers of the HIV test kits listed in Tab 1 of the USAID source/origin waiver for HIV/AIDS diagnostic materials (testing kits) approved in January 2001. In addition, some international procurement agencies and suppliers were also surveyed. The international procurement agencies and suppliers listed in the Management Sciences for Health (MSH) 2000 edition of the *International Drug Price Indicator Guide* (IDPIG) were selected for the survey in addition to the international procurement agent Crown Agents. All the international procurement agencies and suppliers listed in MSH/IDPIG (2000) were contacted, although not all responded. Crown Agents were surveyed as a procurement source available to USAID Missions and CAs under the USAID-funded DELIVER project. Inclusion in this list does not imply that the supplier/agency is endorsed by USAID or MSH/RPM Plus or preferred over any other international supplier/agency.

C. Who Is This Procurement Information Document For?

This document has been developed to assist USAID Mission and CA staff to identify procurement sources for the HIV test kits listed in Tab 1 of the USAID source/origin waiver for HIV/AIDS diagnostic materials (testing kits) for their programs and to plan for procurement. In addition, information is provided to assist in writing requests for approval to procure these HIV test kits using USAID funding.

D. How to Use This Document

This *HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document* is intended to be used by USAID Missions and CAs as an initial reference for identifying manufacturers and international suppliers and for planning for procurement. Prices are given as an indication only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional handling and shipping charges may also apply. Also, because of the time-sensitivity of the procurement information included in this document, the supplier should be contacted to verify the information, particularly with regard to price and availability, before placing an order or preparing a request for USAID approval to procure HIV test kits. This document can also be used by USAID Missions and CAs to compare prices and services offered by local suppliers available in the cooperating country or region to those of the manufacturer or listed international procurement agencies or suppliers.

E. Updates and Evaluation

RPM Plus will monitor the demand and evaluate the usefulness of this procurement information document for USAID Missions and CAs. Given sufficient demand, RPM Plus will update this document annually, after 2002, to reflect both changes in the procurement information and additions or deletions from Tab 1 of the source/origin waiver.

Feedback about the content, utility, ease of use, completeness, and timeliness of information can be e-mailed to rpmplus@msh.org.

F. Guidance Document for Obtaining USAID Approval to Procure USAID-Funded Pharmaceutical Products

During the RPM review of guidelines and procedures for USAID-funded procurement of HIV/AIDS-related pharmaceutical products, the lack of guidance material to assist USAID Missions and CAs in preparing requests for approval to procure HIV/AIDS-related health commodities was also identified as a major constraint. In response, RPM Plus is developing a guidance document for USAID Missions and CAs entitled *Requesting USAID Approval to Procure HIV Test Kits and Other HIV/AIDS-Related Pharmaceutical Products: Guidance and Sources of Information* to provide information on how to apply for approval to procure USAID-funded pharmaceutical products. This guidance document is expected to be available in July 2002. USAID Missions and CAs will be informed when the document is available.

Chapter 2. Information on HIV Test Kits

In January 2001, the USAID Administrator approved a source and origin waiver for HIV/AIDS diagnostic materials (testing kits)[1] to facilitate the process to obtain USAID approval to procure the HIV test kits listed in Tab 1 to the source/origin waiver. The HIV test kits listed in Tab 1 of the source/origin waver have been reviewed by USAID and found to meet all the necessary suitability and price criteria for approval of a source/origin waiver. In addition, the CDC has reviewed and approved the listed kits for safety and efficacy. The list in Tab 1 will be reviewed annually by USAID to determine the adequacy of the source/origin waiver authorities and their continued need. In addition, it will be revised and updated should U.S.-manufactured test kits or new, improved test kits from Geographic Code 935[2] sources become available that meet USAID program requirements. Inclusion in this document does not imply that the product is endorsed by USAID or MSH/RPM Plus or that it is preferred over any other product.

Tab 1, as approved in January 2001 and current as of April 2002, lists the following kits:

BIONOR™ HIV 1&2
Capillus™ HIV
Determine™ HIV-1/2
DoubleCheck™ HIV 1&2
Genie II HIV-1/HIV-2
Hema•Strip™ HIV
HIV SPOT™ – discontinued[3]
HIV*Sav* 1&2 Rapid SeroTest™
Multispot HIV-1/HIV-2
SeroCard™ HIV
Sero•Strip™ HIV

This chapter presents general information on each test kit and is cross-referenced with manufacturer information (Chapter 3) and international procurement agency/supplier information (Chapter 4). See Table 1 for explanatory information relating to the tables that follow for each currently available test kit.[4]

[1] For USAID source and origin waiver for HIV/AIDS diagnostic materials (testing kits), see Annex 1.
[2] For USAID Geographic Codes, see Annex 2.
[3] HIV SPOT™ has been discontinued according to information received from Genelabs Diagnostics Pte Ltd, the manufacturer, January 2002.
[4] The information in this chapter is current as of March 2002.

Table 2. Explanatory Table **Name of HIV Test Kit**

Manufacturer	Name of manufacturer: Look under the manufacturer name in Chapter 3 for more information.
International procurement agency/supplier that stated it stocks/supplies the HIV test kit	Name of international procurement agencies or suppliers who stated that they either stock or can supply the product. Look under the agency/supplier name in Chapter 4 for more information.
Kit available from U.S. sources	This information is useful for writing a request for USAID approval to procure the test kit.
Country where the kit is manufactured (origin)	
FDA approved	
Number of tests per kit	All order quantities must be in multiples of this number because kits are packed from manufacturer in the stated number.
Items included in the kit	Information specifying what is included in the price of the kit and packed as part of kit. Test kit components cannot be ordered separately.
Additional items required but not included	Usually standard laboratory equipment, but some test kits have special requirements.
Shelf life from date of production	The shelf life is the length of time (for rapid HIV test kits, usually months) for which a product can be safely used and accurate results can be expected. Shelf life is dependent upon a product's being stored at conditions specified by the manufacturer.
Language of package insert	Each product has a standard set of information, and a default language in which it appears. It is important that the purchaser know exactly what information and language is standard. Changes to product information, how it is supplied, and in what language must be negotiated and included in the procurement contract.
Storage conditions	Manufacturer-recommended storage conditions. It is essential to follow these recommendations during shipping, storage, and delivery to ensure that the quality and performance of the product are not compromised.
Weight/dimensions/volume	This information is standard for each product. Knowledge of the space requirements will assist programs to plan for adequate storage space. Planning is particularly important where refrigeration is a requirement.
Information obtained from (date)	Person at the company who responded to the survey.

Table 2.1 **BIONOR™ HIV 1&2**

Manufacturer	Bionor A/S
International procurement agency/supplier that stated it stocks/supplies BIONOR™ HIV 1&2	Crown Agents (kits are ordered on demand) Tri-Med Ltd (kits are ordered on demand)
Kit available from U.S. sources	No
Country where the kit is manufactured (origin)	Norway
Kit FDA approved	No
Number of tests per kit	250
Items included in the kit	All necessary consumables (pipettes) and ready-to-use reagents in dropper vials
Additional items required but not included	Requires a BIONOR™ Testing Station that consists of a rocking platform with magnets, aspirator, lamp, and waste container. It is supplied with 4 strips and a lid and can be operated on 220V or 120V (specify when ordering) and on a 12V solar power or car battery. Dimensions of testing station: 35 x 20 x 12 cm (13.8 x 7.9 x 4.7 in) Weight: 4.4 kg (9.7 lb) Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	12 months. No shortening of shelf life after opening of kit. All kit agents are ready to use.
Language of package insert	Currently all instructions are in English; however, for larger orders, instructions in other languages can be provided.
Storage conditions	Store between 2 and 8 degrees C. If stored at room temperature (20–25 degrees C), shelf life is reduced to 4–6 months; if stored at 37 degrees C, shelf life is reduced to 1 month. Do not leave test kits in strong heat or light. If refrigeration space is limited, it is sufficient to store Reagent 1, Reagent 2, Reagent 3, and the positive and negative controls at 2 to 8 degrees C.
Weight/dimensions/volume	4 kits (1000 tests) packed in a polystyrene box for transportation: Wt: 7.35kg (16.17lb) Dimensions: 50.5 x 37 x 23.6 cm (19.9 x 14.6 x 9.3 in) Volume: 44,097 cu cm (0.44 cu m) (2689 cu in [1.56 cu ft]) 1 kit (250 tests): Wt: 1.2 kg (2.64 lb) Dimensions: 21 x 14 x 14 cm (8.3 x 5.5 x 5.5 in) Volume: 4116 cu cm (0.0041 cu m) (251 cu in [0.15 cu ft])
Information obtained from (date)	Birger Sørenson, Managing Director, Bionor A/S (February 2002)

Table 2.2 **Capillus™ HIV**

Manufacturer	Trinity Biotech
International procurement agency/supplier that stated it stocks/supplies Capillus™ HIV	Action Medeor (small stocks are held; generally ordered on receipt of order) Crown Agents (kits are ordered on demand) ECHO Missionpharma A/S (kits are ordered on demand)
Kit available from U.S. sources	No
Country where the kit is manufactured (origin)	Ireland
Kit FDA approved	No
Number of tests per kit	100
Items included in the kit	Reagents, controls, slides, pipettes, disposable pipette tips, interpretation station
Additional items required but not included	Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	15 months
Language of package insert	The insert is generally in English, but other languages may be made available on request.
Storage conditions	Optimum long-term storage is 2–8 degrees C. Stable for short periods (up to 4 weeks) at 25 degrees C. The package insert contains instructions for testing the positive and negative controls if users are concerned that product performance may have been adversely affected by temperature.
Weight/dimensions/volume	1 kit (100 tests) Wt: 0.5 kg (1.1 lb) Dimensions: 22 x 14 x 8 cm (8.7 x 5.5 x 3.1 in) Volume: 2464 cu cm (0.003 cu m) (150.3 cu in [0.09 cu ft])
Information obtained from (date)	Marie McCarthy, Group Product Manager, Trinity Biotech (February 2002)

Table 2.3 **Determine™ HIV-1/2**

Manufacturer	Abbott Laboratories
International procurement agency/supplier that stated it stocks/supplies Determine™ HIV-1/2	Crown Agents (kits are ordered on demand) IDA (kits are ordered on demand) Missionpharma A/S (kits are ordered on demand) Orbi-Pharma Tri-Med Ltd (kits are ordered on demand)
Kit available from U.S. sources	No
Country where the kit is manufactured (origin)	Japan
Kit FDA approved	No
Number of tests per kit	100
Items included in the kit	Test cards and reagents
Additional items required but not included	Pipettes, pipette tips, blood collection equipment For whole blood assay: lancets and EDTA capillary tubes Disposable gloves, biohazard bags, disinfectant
Shelf life from date of production	14 months
Language of package insert	English, French, German, Portuguese, Spanish
Storage conditions	Room temperature (up to 30 degrees C)
Weight/dimensions/volume	1 kit (100 tests) Wt: 0.15 kg (0.33lb) Dimensions: 27 x 16 x 1 cm (10.6 x 6.3 x 0.4 in) Volume: 432 cu cm (0.0004 cu m) (26 cu in [0.015 cu ft])
Information obtained from (date)	Friedah Nehmadi, Senior Product Manager, Abbott Diagnostics Division (ADD) Worldwide (March 2002)

Table 2.4 **DoubleCheck™ HIV 1&2**

Manufacturer	Orgenics Ltd.
International procurement agency/supplier that stated it stocks/supplies DoubleCheck™ HIV 1&2	Crown Agents (kits are ordered on demand) Missionpharma A/S (kits are ordered on demand)
Kit available from U.S. sources	No
Country where the kit is manufactured (origin)	Israel
Kit FDA approved	No
Number of tests per kit	40
Items included in the kit	Tests, reagents, disposable pipettes
Additional items required but not included	Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	15 months
Language of package insert	English, French, Portuguese, Russian, Spanish
Storage conditions	4–8 degrees C (regular refrigerator)
Weight/dimensions/volume	1 kit (40 tests) Wt: 0.8 kg (1.8 lb) Dimensions: 26 x 19 x 14 cm (10.3 x 7.5 x .5 in) Volume: 6916 cu cm (0.0069 cu m) (421.9 cu in [0.244 cu ft])
Information obtained from (date)	Rosanne Tzuk, Export Manager, Orgenics Ltd. (February 2002)

Table 2.5 **Genie II HIV-1/HIV-2**

Manufacturer	BIO-RAD Ltd.
International procurement agency/supplier that stated it stocks/supplies Genie II HIV-1/HIV-2	Crown Agents (kits are ordered on demand) Missionpharma A/S (kits are ordered on demand)
Kit available from U.S. sources	No
Country where the kit is manufactured (origin)	France
Kit FDA approved	No
Number of tests per kit	40
Items included in the kit	Reaction devices and microtubes for diluting specimens
Additional items required but not included	Pipettes and pipette tips Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	12 months
Language of package insert	English, French
Storage conditions	2–8 degrees C. Do not freeze.
Weight/dimensions/volume	1 kit (40 tests) Wt: 1.0 kg (2.2 lb) Dimensions: 26 x 18.5 x 14 cm (10.3 x 7.3 x 5.5 in) Volume: 6934 cu cm (0.0067 cu m) (423.0 cu in [0.245 cu ft])
Information obtained from (date)	Amina Khellaf, Virology International Product Manager, BIO-RAD (February 2002)

Table 2.6 **Hema•Strip™ HIV**

Manufacturer	Chembio Diagnostic Systems, Inc.
International procurement agency/supplier that stated it stocks/supplies Hema•Strip™ HIV	Company distributes direct
Kit available from U.S. sources	Yes, from manufacturer
Country where the kit is manufactured (origin)	United States of America
Kit FDA approved	No
Number of tests per kit	25
Items included in the kit	25 individually packaged tests with sampler, reagents, lancet, and bandage
Additional items required but not included	Timer or stopwatch, rack for holding buffer vials upright (optional), pipettes and pipette tips; blood collection equipment as necessary; disposable gloves, biohazard bags, disinfectant
Shelf life from date of production	12 months
Language of package insert	English, Portuguese, Spanish
Storage conditions	20–33 degrees C
Weight/dimensions/volume	20 kits (500 tests) per shipping carton Wt: 11.3 kg (25 lb) Dimensions: 53.3 x 43.2 x 43.2 cm (27 x 17 x 17 in) Volume: 99,470 cu cm (0.1 cu m) (6067.7 cu in [3.5 cu ft])
Information obtained from (date)	Avi Pelossoff, Director of Sales & Marketing, Chembio Diagnostic Systems, Inc. (February 2002)

Table 2.7 **HIV SPOT™**

Discontinued January 2002	Information from: Genelabs Diagnostics Pte Ltd. 85 Science Park Drive #04-01, The Cavendish Singapore Science Park Singapore 118259 Tel: +65-775-0008 Fax: +65-774-6146 E-mail: genelabs@pacific.net.sg Web site: www.genelabs.com.sg

Table 2.8 **HIV*Sav* 1&2 Rapid SeroTest™**

Manufacturer	Savyon® Diagnostics
International procurement agency/supplier that stated it stocks/supplies HIV*Sav* 1&2 Rapid SeroTest™	Crown Agents (kits are ordered on demand) Missionpharma A/S (kits are ordered on demand)
Kit available from U.S. sources	No
Country where the kit is manufactured (origin)	Israel
Kit FDA approved	No
Number of tests per kit	25 tests per kit and 50 tests per kit
Items included in the kit	Cassettes, reagents, controls, pipettes
Additional items required but not included	Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	12 months
Language of package insert	Usually English, but other languages can be arranged.
Storage conditions	4–8 degrees C
Weight/dimensions/volume	1 kit (25 tests) Wt: 0.385 kg (0.9 lb) Dimensions: 19 x 16 x 11 cm (7.5 x 6.3 x 4.3 in) Volume: 3344 cu cm (0.0033 cu m) (204.0 cu in [0.12 cu ft]) 1 kit (50 tests) Wt: 0.528 kg (1.2 lb) Dimensions: same as for 25 tests/kit Volume: same as for 25 tests/kit
Information obtained from (date)	Elana Bitton, Marketing Assistant, Savyon® Diagnostics (February 2002)

Table 2.9 **Multispot HIV-1/HIV-2**

Manufacturer	BIO-RAD Ltd.
International procurement agency/supplier that stated it stocks/supplies Multispot HIV-1/HIV-2	Crown Agents (kits are ordered on demand) Missionpharma A/S (kits are ordered on demand)
Kit available from U.S. sources	No
Country where the kit is manufactured (origin)	France
Kit FDA approved	No; registration is in progress
Number of tests per kit	50
Items included in the kit	Test cartridges, reagents, disposable transfer pipettes
Additional items required but not included	Disposable glass or plastic test tubes, test tube racks Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	12 months
Language of package insert	English, French
Storage conditions	2–8 degrees C. Do not freeze.
Weight/dimensions/volume	1 kit (50 tests) Wt: 1.265 kg (2.8 lb) Dimensions: 20.4 x 19.5 x 14.5 cm (8.0 x 7.7 x .5.7 in) Volume: 5768 cu cm (0.0058 cu m) (351.8 cu in [0.20 cu ft])
Information obtained from (date)	Amina Khellaf, Virology International Product Manager, BIO-RAD (March 2002)

Table 2.10 **SeroCard™ HIV**

Manufacturer	Trinity Biotech
International procurement agency/supplier that stated it stocks/supplies SeroCard™ HIV	Crown Agents (kits are ordered on demand) Missionpharma A/S (kits are ordered on demand)
Kit available from U.S. sources	Not sold in the United States
Country where the kit is manufactured (origin)	Ireland
Kit FDA approved	No
Number of tests per kit	40
Items included in the kit	Test cards, reagents, disposable pipettes
Additional items required but not included	Timer or stopwatch Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	15 months
Language of package insert	The insert is generally in English, but other languages may be made available on request.
Storage conditions	Optimum storage is 2–8 degrees C.
Weight/dimensions/volume	1 kit (40 tests) Wt: 0.5 kg (1.1lb) Dimensions: 20 x 10 x 14 cm (7.9 x 3.9 x 5.5 in) Volume: 2800 cu cm (0.003 cu m) (170.8 cu in [0.10 cu ft])
Information obtained from (date)	Marie McCarthy, Group Product Manager, Trinity Biotech (February 2002)

Table 2.11 **Sero•Strip™ HIV**

Manufacturer	Chembio Diagnostic Systems, Inc.
International procurement agency/supplier that stated it stocks/supplies Sero•Strip™ HIV	Company distributes direct
Kit available from U.S. sources	Yes, from manufacturer
Country where the kit is manufactured (origin)	United States of America
Kit FDA approved	No
Number of tests per kit	30
Items included in the kit	Test strips, buffer, transfer loops
Additional items required but not included	Timer or stopwatch, tubes for holding buffer/specimen mixture (1ml sampling tubes and disposable cardboard rack available at additional cost) Disposable gloves, biohazard bags, blood collection equipment, disinfectant
Shelf life from date of production	12 months
Language of package insert	English, Spanish
Storage conditions	20–33 degrees C
Weight/dimensions/volume	60 kits (1800 tests) per shipping carton Wt: 9.5 kg (21 lb) Dimensions: 45.7 x 40.6 x 35.6 cm (18 x 16 x 14 in) Volume: 66,052 cu cm (0.07 cu m) (4029.2 cu in [2.3 cu ft])
Information obtained from (date)	Avi Pelossoff, Director of Sales & Marketing, Chembio Diagnostic Systems, Inc. (February 2002)

Chapter 3. Manufacturer Information

This chapter contains procurement information from the manufacturer of each HIV test kit listed in Tab 1 of the USAID source/origin waiver for HIV/AIDS diagnostic materials (testing kits). This information is intended to be used as an initial reference for identifying manufacturers and for planning for procurement. Prices are given as an indicator only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional handling and shipping charges may also apply. Also, because of the time-sensitivity of the procurement information included in this guide, the manufacturer should be contacted to verify the information, particularly with regard to price and availability, before placing an order or preparing a request for USAID approval to procure HIV test kits. Inclusion in this document does not imply that the product or the manufacturer is endorsed by USAID or MSH/RPM Plus or preferred over any other product or manufacturer.

Please consult Table 3's explanatory information before using Tables 3.1 to 3.7.[1]

[1] The information in this chapter is current as of March 2002.

Table 3. Explanatory Table **Name of Manufacturer**

HIV test kits listed in Tab 1 manufactured	Names of the test kits listed in Tab 1 that the manufacturer produces
Listed price (range) and terms or suggested retail price	Prices are given as an indicator only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional handling and shipping charges may also apply. Also, because of the time-sensitivity of the procurement information included in this guide, the manufacturer should be contacted to verify the information before placing an order or preparing a request for USAID approval to procure HIV test kits.
Minimum order quantity	If none is specified, then one kit is the minimum order quantity. Kits cannot be broken up.
Minimum average shelf life on delivery	The length of time (usually months) for which a product can be safely used and accurate results can be expected. Shelf life is dependent upon a product's being stored at conditions specified by the manufacturer, and these instructions *must* be included with every package, carton, and/or shipped unit. The minimum acceptable shelf life on delivery must be negotiated and included in the procurement contract.
Is stock maintained or is the kit manufactured on demand?	If stock is held on hand then the lead time is generally faster. However, having the kits manufactured on receipt of the order has the advantage of a longer shelf life.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Information to assist programs in planning for procurement to ensure that orders are placed in sufficient time to avoid stock outages
Required payment method	Any general requirements for method of payment are given. These requirements are often country, program, or quantity specific. Contact the manufacturer for further information.
How are quality problems with test kits addressed?	Information on the company policy if the customer reports problems with the quality of test kits purchased
Contact information for manufacturer	
Other information	Includes information on local country offices
Information obtained from (date)	Name of the person at the company who responded to the survey

Table 3.1 **Abbott Laboratories**

HIV test kits listed in Tab 1 manufactured	Determine™ HIV-1/2
Listed price (range) and terms or suggested retail price	Price per kit USD 120 (100 tests) FOB (shipping costs are extra) for not-for-profit organizations for volumes in the thousands. Price is dependent on quantities purchased and is determined by the country-specific Abbott Diagnostics Division (ADD) office.
Minimum order quantity	None
Minimum average shelf life on delivery	Usually close to 14 months because Abbott has an office in most countries
Is stock maintained or is the kit manufactured on demand?	Stocks are generally held in most countries so orders can be filled promptly.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Because stocks are local, should not be long
Required payment method	Country dependent
How are quality problems with test kits addressed?	ADD country office is responsible for product complaints. Client is asked to return the kit to Abbott for testing. If a defect is confirmed, the kit is replaced free of charge.
Contact information for manufacturer	Friedah Nehmadi, Senior Product Manager Abbott Diagnostics Division (ADD) Worldwide 100 Abbott Park Road Dept. 09L4, Building AP6C 4th Floor Abbott Park, IL 60064 USA Tel: +1 847 935 8771 Fax: +1 847 937 2776 E-mail: friedah.nehmadi@abbott.com Web site: www.abbottdiagnostics.com
Other information	Contact ADD Worldwide for contact information for ADD country office.
Information obtained from (date)	Friedah Nehmadi, Senior Product Manager, Abbott Diagnostics Division (ADD) Worldwide (March 2002)

Table 3.2 **Bionor A/S**

HIV test kits listed in Tab 1 manufactured	BIONOR™ HIV 1&2
Listed price (range) and terms or suggested retail price	Price per test kit (250 tests) varies from USD 300 to 825 ex-warehouse (FOB price). Shipping and insurance are extra. USD 825 price includes one Bionor Testing Station per 25,000 tests. Prices may vary according to quantities ordered and whether supplied direct or through a distributor. No additional handling charges. Price of testing station: From USD 900 to 1,500 depending on quantity ordered. Shipping and insurance are extra. Price can be incorporated into price per test kit. No additional handling charges.
Minimum order quantity	250 tests (1 kit), but preferably not less than 1000 tests (4 kits), which is 1 export polystyrene box
Minimum average shelf life on delivery	10 months
Is stock maintained or is the kit manufactured on demand?	Some stocks are held (approx. 50 kits). However, to obtain the best possible shelf life, kits are mostly manufactured on demand.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	1 day if supplied from stocks held Approx. 3–4 weeks if a new batch is manufactured
Required payment method	Prefer prepayment or letter of credit. Also use cash against documents or MasterCard/Visa credit card.
How are quality problems with test kits addressed?	Normally replace the kit. If problems are reported with a kit, Bionor A/S runs a control on reference kit of same batch. Actions taken depend on outcome of testing.
Contact information for manufacturer	Mr. Birger Sørenson, Managing Director Bionor A/S P.O. Box 1868 NO-3703 Skien Norway Tel: +47 35 50 57 50 Fax: +47 35 50 57 01 E-mail: Birger.Sorenson@bionor.no Web site: www.bionor.no

Other information	Kits can be purchased directly from the manufacturer in Norway. Small quantities are dispatched by courier and larger quantities by air cargo. Orders are generally delivered to a single address in a country although the company has worked with the Ministry of Health in some countries to develop an in-country distribution system. Main distributors used: Uganda: Achelis (Uganda) Ltd., Kampala (James Segawa, tel: +256 41 344 442, achelis@infocom.co.ug) South Africa: The Scientific Group, Johannesburg, (Mike Thomson, tel: +27 11 652 4000, miket@scientificgroup.com) Worldwide: Martin James Medical, UK (Brian Hobbs, tel: +44 1326 280776, bhobbs@martinjames.com)
Information obtained from (date)	Birger Sørenson, Managing Director, Bionor A/S (February 2002)

Table 3.3 **BIO-RAD Ltd.**

HIV test kits listed in Tab 1 manufactured	Genie II HIV-1/HIV-2 and Multispot HIV-1/HIV-2
Listed price (range) and terms or suggested retail price	Genie II HIV-1/HIV-2 (FOB prices, shipping and insurance extra): 3 kits USD 138 per kit 30 kits USD 125 per kit 300 kits USD 111 per kit Multispot HIV-1/HIV-2 (FOB prices, shipping and insurance extra): 3 kits USD 379 per kit 30 kits USD 348 per kit 300 kits USD 316 per kit Prices depend on customer (distributors, end users, or tenders) and quantities ordered.
Minimum order quantity	Value of USD 280
Minimum average shelf life on delivery	Genie II HIV-1/HIV-2 shelf life 6–9 months Multispot HIV-1/HIV-2 shelf life 6–9 months
Is stock maintained or is the kit manufactured on demand?	Stock is available to cover an average 1.5-months of sales. However, extra-large quantities will either be staggered deliveries or need to be ordered a minimum of two months in advance.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Usually 9 days but can be longer for unforecasted orders (see above)
Required payment method	Orders for more than USD 14,000 require letter of credit. Orders between USD 7,000–14,000, 50 percent required in advance and 50 percent on delivery. 30 days credit given for orders less than USD 7,000.
How are quality problems with test kits addressed?	Complaints should be addressed to technical support in BIO-RAD France. Complaints are then investigated. If the complaint is justified, the product is either replaced or a credit note issued.
Contact information for manufacturer	Amina Khellaf Virology International Product Manager BIO-RAD France 3 Boulevard Raymond Poincaré 92430 Marnes La Coquette France Tel: +33-1-4795-6018 Fax: +33-1-4795-6186 E-mail: amina.khellaf@bio-rad.com Web site: www.bio-rad.com
Other information	Delivery worldwide to any address. Have more than 20 subsidiaries and many distributors. Contact manufacturer for list.
Information obtained from (date)	Amina Khellaf, Virology International Product Manager, BIO-RAD (February 2002)

Table 3.4 Chembio Diagnostic Systems, Inc.

HIV test kits listed in Tab 1 manufactured	Hema•Strip™ HIV and Sero•Strip™ HIV
Listed price (range) and terms or suggested retail price	Hema•Strip™ HIV: Less than 250,000 tests: USD 2.00 per test Greater than 250,000 tests: To be determined Sero•Strip™ HIV: Less or equal to 10,000 tests: USD 1.25 per test Greater than 10,000 tests: USD 1.00 per test Price for both kits varies according to quantity ordered and customer/user.
Minimum order quantity	For Hema•Strip™ HIV: 20 kits (500 tests) For Sero•Strip™ HIV: 10 kits (300 tests)
Minimum average shelf life on delivery	10 months
Is stock maintained or is the kit manufactured on demand?	Substantial stocks are held
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	If in stock, 2–3 days to dispatch If specially manufactured, 2–4 weeks Company advises to work on a 2–4 week lead time.
Required payment method	U.S. government purchase orders are accepted. Others must prepay or set up open letter of credit.
How are quality problems with test kits addressed?	All performance problems must be addressed to company's QA/QC Manager.
Contact information for manufacturer	Avi Pelossof, Director of Sales & Marketing Chembio Diagnostic Systems, Inc. 3661 Horseblock Road Medford, NY 11763 USA Tel: +1 631 924-1135 Fax: +1 631 924 6033 E-mail: avi@chembio.com Web site: www.chembio.com or www.salv.com
Other information	Based on FDA Export Regulations, cannot ship within the United States. Certain documents are required from importing countries. Deliver directly to customer; no distributors used.
Information obtained from (date)	Avi Pelossoff, Director of Sales & Marketing, Chembio Diagnostic Systems, Inc. (February 2002)

Table 3.5 **Orgenics Ltd.**

HIV test kits listed in Tab 1 manufactured	DoubleCheck™ HIV 1&2
Listed price (range) and terms or suggested retail price	Reference price not given. Price depends on quantities ordered.
Minimum order quantity	None
Minimum average shelf life on delivery	12–14 months
Is stock maintained or is the kit manufactured on demand?	Have a large stock available but may manufacture on demand depending on quantities ordered
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	From stock: Orders are dispatched immediately. If order is a special manufacture: 2–3 weeks.
Required payment method	Preferably bank transfer
How are quality problems with test kits addressed?	Information not given
Contact information for manufacturer	Rosanne Tzuk, Export Manager Orgenics Ltd. P.O. Box 360 Yavne 70650 Israel Tel: +972-8-9201 Fax: +972-8-9438758 E-mail: rosanne@orgenics.co.il Web site: www.orgenics.com
Other information	Kits are supplied through numerous distributors worldwide. Contact Orgenics head office or visit Web site www.orgenics.com for distributor contact information.
Information obtained from (date)	Rosanne Tzuk, Export Manager, Orgenics Ltd. (February 2002)

Table 3.6 **Savyon® Diagnostics**

HIV test kits listed in Tab 1 manufactured	HIV*Sav* 1&2 Rapid SeroTest™
Listed price (range) and terms or suggested retail price	Reference price per test: USD 1.50 FOB, shipping and insurance are extra. Prices vary according to quantities ordered.
Minimum order quantity	None
Minimum average shelf life on delivery	10 months
Is stock maintained or is the kit manufactured on demand?	Some stock held, quantity not specified
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	If supplied from stock: immediate dispatch If order is specially manufactured: 4 weeks
Required payment method	Letter of credit, prepayment, or open account is possible depending on the customer.
How are quality problems with test kits addressed?	The product is replaced.
Contact information for manufacturer	Elana Bitton, Marketing Assistant Savyon Diagnostics Ltd. 3 Habosem Street Ashdod, 77610 Israel Tel: +972 8 856 2929 Ext. 202 Fax: +972 8 852 3176 E-mail: elana@savyon-d.co.il Web site: www.hctech.com
Other information	Deliver to distributors
Information obtained from (date)	Elana Bitton, Marketing Assistant, Savyon Diagnostics Ltd. (February 2002)

Table 3.7 **Trinity-Biotech**

HIV test kits listed in Tab 1 manufactured	Capillus™ HIV and SeroCard™ HIV
Listed price (range) and terms or suggested retail price	Capillus™ HIV USD150–175 per kit (100 tests) SeroCard™ HIV USD 60–70 per kit (40 tests) Prices for both kits are ex-warehouse (FOB price) and include all handling charges. Shipping and insurance are extra. Prices may vary by quantity and region.
Minimum order quantity	Capillus™ HIV: 5 kits (500 tests) SeroCard™ HIV: 5 kits (40 tests)
Minimum average shelf life on delivery	Both kits are generally delivered with 9–13 months shelf life.
Is stock maintained or is the kit manufactured on demand?	Stocks are held, but levels vary with demand.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Lead time is 4 weeks.
Required payment method	Three up-front payments, after which credit terms can be established. Credit card orders can be accepted.
How are quality problems with test kits addressed?	In the event of a problem with a product, the query is investigated through the in-house quality system. If a product problem is confirmed, replacement product or credit notes are issued.
Contact information for manufacturer	Marie McCarthy, Group Product Manager Trinity Biotech PLC Bray, Co Wicklow, Ireland Tel: +353 1 2769828 Fax: +353 1 2769881 E-mail: mmcarthy@trinitybiotech.ie Web site: www.trinitybiotech.com
Other information	Depending on the freight agent selected, it is possible to deliver door to door, but freight charges and customs clearance are the responsibility of the customer or its freight agent. Contact the manufacturer or visit the Web site www.trinitybiotech.com for information on in-country distributors.
Information obtained from (date)	Marie McCarthy, Group Product Manager, Trinity Biotech (February 2002)

Chapter 4. International Procurement Agency and Supplier Information

This chapter contains rapid HIV test kit procurement information from selected international procurement agencies and suppliers. All the international procurement agencies and suppliers listed in the MSH 2000 edition of the *International Drug Price Indicator Guide* were surveyed, although not all responded. In addition, Crown Agents were also surveyed as a procurement source available under the USAID-funded DELIVER project. Inclusion in this document does not imply that the supplier/agency is endorsed by USAID or MSH/RPM Plus or preferred over any other international supplier/agency.

A supplier maintains a warehouse and supplies items directly to customers. The following international suppliers responded to the survey:

Action Medeor
Equipment for Charitable Hospitals Overseas (ECHO) International Health Services
International Dispensary Association (IDA)
ORBI-PHARMA

A procurement agency negotiates prices and places purchase orders for clients and may often order from a vendor such as those listed in this document. The procurement agency usually charges a fee for its service over and above the drug's CIF[1] price. The following international procurement agencies responded to the survey:

Crown Agents
Missionpharma A/S
Tri-Med Ltd.

The information included here is intended to be used as an initial reference for identifying international procurement agencies and suppliers and for planning for procurement. Prices are given as an indication only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional handling and shipping charges may also apply. Also, because of the time-sensitivity of the procurement information included in this guide, the supplier or agency should be contacted to verify the information, particularly with regard to price and availability, before placing an order or preparing a request for USAID approval to procure HIV test kits.

Please consult the explanatory information included in Table 4 before using Tables 4.1 to 4.7.[2]

[1] CIF prices include cost, insurance, and freight.

[2] The information in this chapter is current as of March 2002.

Table 4. Explanatory Table **Name of International Agency/Supplier**
Specifies if the entity is an international procurement agency or supplier

HIV test kits listed in Tab 1 stocked/supplied	Names of the test kits listed in Tab 1 that the international procurement agency/supplier stocks/ supplies
Listed price (range) and terms or suggested retail price	Prices are given as an indicator only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional handling and shipping charges may also apply. Also, because of the time-sensitivity of the procurement information included in this guide, the international procurement agency/supplier should be contacted to verify the information prior to placing an order or preparing a request for USAID approval to procure HIV test kits.
Minimum order quantity	If none is specified, then one kit is the minimum order quantity. Kits cannot be broken up.
Minimum average shelf life on delivery	The length of time (usually months) for which a product can be safely used and accurate results can be expected. Shelf life is dependent upon a product's being stored at conditions specified by the manufacturer, and these instructions *must* be included with every package, carton, and/or shipped unit. The minimum acceptable shelf life on delivery must be negotiated and included in the procurement contract.
Is stock maintained or is the kit ordered on demand?	If stock is held on hand, then the lead time is generally faster. However, having the kits manufactured on receipt of the order has the advantage of a longer shelf life.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Information to assist programs in planning for procurement to ensure that orders are placed in sufficient time to avoid stock outages.
Required payment method	Any general requirements for method of payment are given. These requirements are often country, program, or quantity specific. Contact the international procurement agency/supplier for further information.
How are quality problems with test kits addressed?	Information on the company policy if the customer reports problems with the quality of test kits purchased
Contact information	
Other information	Includes information on delivery
Information obtained from (date)	Name of the person at the company who responded to the survey

Table 4.1 **Action Medeor**
International Supplier

HIV test kits listed in Tab 1 stocked/supplied	Capillus™ HIV
Listed price (range) and terms or suggested retail price	Not given Prices are ex-warehouse. Transportation costs are extra. Service charge: 1% of total value
Minimum order quantity	None
Minimum average shelf life on delivery	Capillus™ HIV: 12 months
Is stock maintained or is the kit ordered on demand?	A small stock is maintained; otherwise, kits are ordered on demand.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Immediately if supplied from stock 2–4 weeks if ordered on demand
Required payment method	Normally upon receipt of invoice or up front for first-time orders. Agreed case by case.
How are quality problems with test kits addressed?	The kits are either replaced or refund given.
Contact information	Dr. Ilse Schleiden-Schmidt Action Medeor Deutsches Medikamenten-Hilfswerk St. Töniser Strasse 21 D-47918 Tönisvorst Germany Tel: 49-21-56-97-88-92 Fax: 49-21-56-97-88-88 E-mail: Schleiden-Schmidt@medeor.org Web site: www.medeor.org (German only)
Other information	Deliver to facilities within a country
Information obtained from (date)	Ursula Geller, Action Medeor (January 2002)

Table 4.2 **Crown Agents**
International Procurement Agency

HIV test kits listed in Tab 1 supplied	As a procurement agency, Crown Agents do not stock test kits but procure on receipt of an order. They report having sourced, procured, and supplied the majority of kits listed in Tab 1.
Listed price (range) and terms or suggested retail price	Product dependent, includes all handling charges. Shipping and insurance charges are extra. Also levy a procurement charge based on a sliding scale according to value of the order. Scales are agreed with individual clients. Commitment to long-term agreement can result in lower prices.
Minimum order quantity	None
Minimum average shelf life on delivery	Product dependent. Try to procure freshly manufactured products to maximize shelf life at delivery.
Is stock maintained or is the kit ordered on demand?	Ordered on demand
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Between 2 to 6 weeks
Required payment method	Prefer payment at time of order. Other options can be discussed.
How are quality problems with test kits addressed?	Normally arrange an urgent resupply with a refund at a later date
Contact information	In USA Jennifer Katzka, General Manager Crown Agents Consultancy Incorporated 818 Connecticut Avenue, NW Suite 840 Washington, DC 20006, USA Tel: +1 202 822 8052 Fax: +1 202 822-8064 E-mail: jkatzka@crownagents.com In UK Lee Chacksfield Senior Medical Procurement Manager Crown Agents Tel: +44 0208 643 3311 E-mail: lee.chacksfield@crownagents.co.uk Web site: www.crownagents.com
Other information	Can deliver direct to a customer or to a distributor depending on client's requirements. Contact head office or see Web site www.crownagents.com for list of in-country representative offices.
Information obtained from (date)	Nicola Golding, Crown Agents (January 2002)

Table 4.3 **ECHO**
International Supplier

HIV test kits listed in Tab 1 stocked/supplied	Capillus™ HIV
Listed price (range) and terms or suggested retail price	Single kit: USD 206 25 kits or more: USD 198 per kit 100 kits or more: USD 190 per kit Prices include service charge, but shipping is extra.
Minimum order quantity	One kit
Minimum average shelf life on delivery	15 months
Is stock maintained or is the kit ordered on demand?	Stock is held at ECHO
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Maximum 7 days from stock. Varies according to the size of the order. Maximum 21 days if special ordered.
Required payment method	For first-time customers: Advance payment Established ECHO customers: 30 days on submission of invoice Special terms are agreed with international nongovernmental organizations (NGOs), UN, WHO, governments, and some national NGOs in developing countries.
How are quality problems with test kits addressed?	Product Recall and Return Procedure includes replacement and refunding.
Contact information	June Vincent Head of Sales ECHO International Health Services Ltd. Ullswater Crescent Coulsdon, Surrey, CR5 2HR UK Tel: +44 (0) 20 8660 2220 Fax: +44 (0) 20 8668 0751 E-mail: bfunda@echohealth.org.uk Web site: www.echohealth.org.uk
Other information	Deliver to wherever goods are consigned. Services nonprofit humanitarian projects and governments only.
Information obtained from (date)	Bonnie Fundafunda, ECHO (January 2002)

Table 4.4 **IDA**
International Supplier

HIV test kits listed in Tab 1 stocked/supplied	Determine™ HIV-1/2
Listed price (range) and terms or suggested retail price	EURO 170 per kit (100 tests) FOB, shipping and insurance extra Prices are available in printed and electronic catalogues on request. Handling fee of 1.5% of the value of the goods, minimum fee EURO 45
Minimum order quantity	None
Minimum average shelf life on delivery	Determine™ HIV-1/2: 12 months
Is stock maintained or is the kit ordered on demand?	Stocks of Determine™ HIV-1/2 are kept low and ordered on demand.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	2–3 weeks; overnight for emergency orders
Required payment method	Usually goods are shipped on receipt of payment. For large orders and tenders, will work with letters of credit.
How are quality problems with test kits addressed?	Depends on the nature of the problem and on the preferred solution of the customer
Contact information	Ron Wehrens, Pharmacist Sales and Marketing Support IDA Foundation P.O. Box 37098 1030 AB Amsterdam The Netherlands Tel: +31 20 4033051 Fax: +31 20 4031854 E-mail: rwehrens@ida.nl Web site: www.ida.nl
Other information	Usually send goods to a single address but can use a courier to deliver to multiple addresses in country. IDA is a nonprofit wholesaler and only supplies to nonprofit organizations and governments.
Information obtained from (date)	Ron Wehrens, IDA (January 2002)

Table 4.5 **Missionpharma A/S**
International Procurement Agency

HIV test kits listed in Tab 1 supplied	As a procurement agency, Missionpharma A/S does not stock test kits but procures on receipt of an order.
Listed price (range) and terms or suggested retail price	Product dependent, shipping charges are extra. Commitment to long-term agreement can result in lower prices. Price includes handling charges.
Minimum order quantity	None
Minimum average shelf life on delivery	Product dependent
Is stock maintained or is the kit ordered on demand?	Ordered on demand
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Depends on manufacturer, usually between 1–2 weeks
Required payment method	30 days from invoice
How are quality problems with test kits addressed?	Complaints related to product quality are handled according to written instructions by the quality department in cooperation with the sales and purchase departments as well as the company management. A thorough investigation is initiated in order to establish a cause for the possible quality problem. All customer complaints are filed and trended in order to make sure that appropriate corrective actions are taken to prevent recurrence of quality problems and to trend problems related to specific manufacturers. Kit will be replaced or a refund issued as per customer preference.
Contact information	Jens V. Rasmussen Area Sales Manager Missionpharma A/S Vassingeroedvej 9 DK-3540 Lynge Denmark Tel: +45 48 163200 Fax: +45 48 163248 E-mail: jr@missionpharma.com info@missionpharma.com Web site: www.missionpharma.com
Other information	Can deliver to single address or multiple facilities in the receiving country.
Information obtained from (date)	Jens V. Rasmussen, Missionpharma A/S (January 2002)

Table 4.6 **ORBI-PHARMA**
International Supplier

HIV test kits listed in Tab 1 stocked/supplied	Determine™ HIV-1/2
Listed price (range) and terms or suggested retail price	Varies according to quantities ordered. Determine™ HIV-1/2: one single kit: EURO 227.53 FOB. Includes handling charges but shipping and insurance are extra.
Minimum order quantity	None
Minimum average shelf life on delivery	Determine™ HIV-1/2: 6 months
Is stock maintained or is the kit ordered on demand?	Stock is held in warehouse in Germany.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	Depends on quantity ordered. Average of 2 weeks.
Required payment method	Negotiable
How are quality problems with test kits addressed?	Kits are recalled and replaced.
Contact information	Miek Delaere/Chantal Dauw Order Department ORBI-PHARMA Molenberglei 18 B-2627 Schelle Belgium Tel: +32 3 880 6360 Fax: +32 3 888 7481 E-mail: info@orbi-pharma.be Web site: http://user.online.be/orbipharma
Other information	None
Information obtained from (date)	Chantal Dauw, ORBI-PHARMA (March 2002)

Table 4.7 **Tri-Med Ltd.**
International Procurement Agency

HIV test kits listed in Tab 1 supplied	BIONOR™ HIV 1&2 Determine™ HIV-1/2
Listed price (range) and terms or suggested retail price	Prices vary according to many factors: quantity ordered, customer, final destination, required delivery time, terms of payment. An additional handling charge of USD 20 is applied to each order. BIONOR™ HIV 1&2 price is ex-warehouse (shipping is extra) and includes handling charges. Determine™ HIV-1/2 price is ex-warehouse (shipping is extra).
Minimum order quantity	None
Minimum average shelf life on delivery	BIONOR™ HIV 1&2: 10 months Determine™ HIV-1/2: Information not available
Is stock maintained or is the kit ordered on demand?	Kits are ordered on demand. Some small stocks held.
Average time taken to fill an order (from receipt of order to dispatch of goods from warehouse)	3–4 days if supplied from stock. 3–4 weeks for freshly manufactured stock
Required payment method	Up front on first order, thereafter against documents. Terms established by negotiation.
How are quality problems with test kits addressed?	Kits are replaced.
Contact information	Neville Vickers Tri-Med Limited 7, Hanson Street London W1W 6TE UK Tel: +44 20 7637 1601 Fax:+44 20 7255 1000 E-mail: vickers@tri-med.com Web site: www.tri-med.com
Other information	Normally deliver to a single destination (port or airport) but can arrange packing and transport to multiple destinations.
Information obtained from (date)	Neville Vickers, Tri-Med Limited (January 2002)

Annex 1. USAID Source/Origin Waiver for HIV Test Kits

[Approved by J. Brady Anderson, USAID Administrator, on January 11, 2001, and effective from this date.]

January 11, 2001

ACTION MEMORANDUM

TO: The Administrator

FROM: A-AA/G Barbara Turner /s/

SUBJECT: The HIV/AIDS and Infectious Disease Initiatives: Source and Origin Waiver for HIV/AIDS Diagnostic Materials (testing kits)

ISSUE FOR DECISION

Whether to authorize the procurement of testing kits from Code 935 countries (any country or area excluding foreign policy restricted countries).

ESSENTIAL FACTORS

In a December 19, 2000, Action Memorandum (See Tab 2) you approved certain waivers and expedited procedures to acquire services and commodities for the Agency's HIV/AIDS and Infectious Disease Initiatives. While the December 19th Memorandum authorizes expedited procurement procedures for testing kits, it does not waive source and origin requirements because more research was required on their availability in the United States and the efficacy and cost of offshore testing kits.

Having completed this research, we are seeking your approval of a source and origin waiver from Geographic Code 000 (United States) to Geographic Code 935 for specific testing kits identified in Tab 1. Consistent with the December 19th Memorandum, your approvals below will be in effect through the year 2007 and apply to all sources of funds including prior year funds. Records will be kept on all uses of the waiver authorities. Annual reviews will determine the adequacy of the waiver authorities and their continuing need. The list at Tab 1 will be revised and updated should U.S. manufactured testing kits, or new or improved testing kits from Geographic

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Code 935 sources become available that meet USAID program requirements.

Effective counseling and testing for HIV is a critical component of any HIV/AIDS strategy. While testing provides information to individuals regarding their HIV status, it also provides information regarding the extent of the epidemic among target groups and indicates where additional resources may be needed. We anticipate that between one million to three million testing kits will be purchased annually over the seven-year life of the HIV/AIDS initiative. At an estimated average cost of $3 per test, the aggregate procurement value will be approximately 45 to 55 million dollars. However, this amount will be substantially reduced if, as expected, the average cost per testing kit is reduced as new products come on stream.

The applicable statute and regulations covering USAID's "buy America" requirements and pharmaceutical requirements (including testing kits) appear in section 604(a) of the Foreign Assistance Act, ADS section 312.5.3c(2), and in 22 CFR 228. Taken together, these sometimes overlapping regulations provide that pharmaceuticals be purchased outside of the United States only if information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the Food and Drug Administration (FDA) or other U.S. controlling authority. ADS section E312.5.3c(3) adds a further requirement that patent laws be honored. Such items may be purchased in Geographic Code 935 countries if you determine that: 1) the items are not produced or available in the United States, or if available, they cost more than 50 percent of comparable items, or 2) offshore procurement is necessary to promote efficiency in the use of foreign assistance resources and avoid impairment of foreign assistance objectives. While the United States Centers for Disease Control and Prevention (CDC) is not a controlling authority, approval by CDC is good evidence that may be used as a basis for authorizing non-U.S. procurement of products that are not approved by the FDA.

With respect to test kits, the criteria supporting a waiver are met. The most commonly available United States testing kits are based on the Elisa Reader method. The cost per test of these kits is approximately $20. This cost is more than 50 percent higher than the cost of offshore alternatives. Further, these products require high quality lab facilities and highly trained personnel that are not

widely available in target countries. Even where this kind of physical and human infrastructure is available in urban centers, there are insurmountable logistical problems in transporting thousands of blood specimens to and from rural sites to urban laboratories. It takes days or weeks to obtain tests results using the Elisa Reader method. This is too long, given that in some target countries more than 30 percent of clients tested by these systems fail to return for the test results.

Recently, a new "simple-rapid" type of HIV test costing $1-3 per test has become available offshore. These tests are easy to use, no central laboratory is needed, and they deliver test results within a few hours instead of days to weeks. There is currently only one United States-manufactured HIV rapid test that is FDA approved. It costs about $9 and the manufacturer has recently suspended production of this product.

Tab 1 contains a list of testing kits that have been reviewed internally and found to meet all the necessary suitability and price criteria in the applicable waiver regulations cited above. CDC has reviewed and approved the items on the Tab 1 list for safety and efficacy.

RECOMMENDATIONS

A. We recommend that, based on the findings above, you authorize the procurement in Code 935 countries of testing kits identified in Tab 1.

Approve_____

Disapprove_____

Date_____

B. We recommend that you delegate authority to AA/M to amend the Tab 1 approved list from time to time to add new Code 935 testing kits when they meet the same criteria.

Approve_____

Disapprove_____

Date_____

Attachments:

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Tab 1 – Approved List of Testing Kit Products and Manufacturers
TAB 2 - December 19, 2000 Action Memo
[Omitted here]

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CLEARANCE PAGE FOR ACTION MEMORANDUM requesting a source and origin waiver for HIV/AIDS diagnostic testing kits for the HIV/AIDS and Infectious Disease Initiative.

Clearances:

AA/LPA:JCrapa_____Date_____
AA/PPC:TFox_____Date_____
DAA/G:DGillespie_____Date_____
A-AAM:RNygard_____Date_____
GC:SMcAllister_____Date_____
ES:RConroy_____Date_____
M:MWard_____Date_____

Draft:G/PHN:AGetson, RKirkland 12/20/00; Revised GC:RMeighan, MKitay 1/9/01

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Tab 1 - Approved List of Testing Kit Products and Manufacturers

Product	Price in Dollars	Source Country	Manufacturer
Bionor	NA	Norway	Bionor A/S
Capillus	$1.50	Ireland	Trinity Biotech*
Determine	$3.80	Japan	Abbott Laboratories*
DoubleCheck	$1.35	Israel	Orgenics
Genie II	NA	France	Sanofi Diagnostics Pasteur
Hema-Strip	$3.00	Singapore	Saliva Diagnostics, Ltd.*
HIV Spot	$1.20	Singapore	Genelabs Diagnostics*
HIVSav	NA	Israel	Sayvon Diagnostics Ltd.
MultiSpot	$4.00	France	Sanofi Diagnostics Pasteur*
SeroCard	$1.80	Ireland	Trinity Biotech*
Sero-Strip	$1.50	Israel	Saliva Diagnostic Systems, Ltd.*
* Parent Company is a United States based firm			

USAID Geographic Code	Description
Code 000 – The United States	The United States of America, any State(s) of the United States, the District of Columbia, and areas of U.S.-associated sovereignty, including commonwealths, territories, and possessions.
Code 899 – Free World	Any area or country, except the cooperating country itself and the following foreign policy restricted countries: Afghanistan, Libya, Vietnam, Cuba, Cambodia, Laos, Iraq, Iran, North Korea, Syria and the People's Republic of China.
Code 935 – Special Free World	Any area or country in the Free World including the cooperating country, but excluding the foreign policy restricted countries.
Code 941 – Selected Free World	The United States and any independent country in the Free World (excluding foreign policy restricted countries), except the cooperating country itself and the following: Albania, Andorra, Angola, Armenia, Austria, Australia, Azerbaijan, Bahamas, Bahrain, Belgium, Bosnia and Herzegovina, Bulgaria, Belarus, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Gabon, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Kazakhstan, Kuwait, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia*, Malta, Moldova, Monaco, Mongolia, Montenegro*, Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russia, Sa Marino, Saudi Arabia, Serbia*, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan*, Tajikistan, Turkmenistan, Ukraine, United Arab Emirates, United Kingdom, Uzbekistan, and Vatican City. * Has the status of "Geopolitical Entity" rather than independent country.